Nos. 336, 438

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Supreme Court of the United States

OCTOBER TERM, 1966

THE TOILET GOODS ASSOCIATION, INC., ET AL., *Petitioners,*

v.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, and JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS, *Respondents.*

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, and JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS, *Petitioners,*

v.

THE TOILET GOODS ASSOCIATION, ET AL., *Respondents.*

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR PETITIONERS IN NO. 336 AND FOR RESPONDENTS IN NO. 438

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Question Presented.

Whether members of an industry* affected by final agency regulations can challenge their validity in equity for an injunction and under the Declaratory Judgments and Administrative Procedure Acts, where:

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* The complaint is by 39 companies which manufacture cosmetics and their trade association, whose members represent over 90% of industry sales (R. 2-5).

(a) The regulations are challenged as in excess of the agency's statutory authority, and their validity turns on questions of statutory construction which do not involve agency expertise;

(b) The regulations impose new requirements which necessitate drastic alteration of business practices involving substantial expense and irrevocable harm, and have an immediate and substantial impact on the industry, including exposure of valuable trade secrets;

(c) The challenge is against four provisions interrelated as elements of a common plan of agency regulation;

(d) Non-compliance with any of such four provisions could cause the product affected to be banned from the market and, if thereafter sold, entail civil and criminal prosecution, seizure proceedings and harmful administrative actions; and

(e) The power and authority assumed by the agency in the regulations are substantially the same power and authority sought in agency sponsored legislation, but which Congress withheld.

Statutes and Regulations Involved.

This case involves the Declaratory Judgments Act (§274D, Jud. Code (1934), 28 U.S.C. §§2201-02); the Administrative Procedure Act (60 Stat. 243 (1946), 5 U.S.C. §551, *et seq.*); the Federal Food, Drug and Cosmetic Act (52 Stat. 1040 (1938)), as amended by the Color Additive Amendments of 1960 (74 Stat. 397 (1960), 21 U.S.C. §§321(t)(1), 361, 371, 374, 376); and the Color Additives Regulations (28 Fed. Reg. 6439 (June 22, 1963), 21 C.F.R. 8.1 *et seq.*, §§8.1(f)(m)(u), 8.4, 8.26, 8.28, 8.30(a), 8.50 and 8.51(a)). The relevant portions not included in petitioners'* Appendix are in the Appendix to this brief.

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* Consistent with the Government's brief (Br. 4, fn. 3), the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs, petitioners in No. 438 and respondents in

Statement.

Introduction.

The case involves the validity of four provisions of regulations issued June 22, 1963 by the Commissioner of Food and Drugs ("FDA"), entitled "Color Additives" (the "Regulations") (28 Fed. Reg. 6439, 21 C. F. R. 8.1 *et seq.*). The Regulations were promulgated under the "Color Additive Amendments of 1960" (74 Stat. 397, 21 U. S. C. §321) (the "Amendments"), which amended the Federal Food, Drug, and Cosmetic Act (the "Act").

The Amendments require FDA listing of "color additives" "for use in or on" food, drugs and cosmetics "if and to the extent that such additives are suitable and safe for any such use" (§706(b)(1) of the Act),* and subsequent certification "of batches of color additives" which have been listed, unless exempted from certification (§706(c)). Color additives so used and not listed and certified are "deemed unsafe" (§706(a)). Food, drug and cosmetic products which contain color additives thus "deemed unsafe" are "deemed to be adulterated" (§§402(c), 501(a)(4)(A), 601(e)), and their sale entails drastic criminal and civil penalties, including multiple seizures (§§301(a), 302, 303, 304).

The four provisions of the Regulations involved in this case, each of which is the subject of a separate count in the complaint, accomplish the following:

(1) Require listing, after prescribed tests, and certification, of all finished cosmetic products which impart

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No. 336, are herein referred to as "petitioners"; respondents in No. 438 and petitioners in No. 336 are herein referred to as "respondents."

* Consistent with the Government's brief, references to sections of the statute will be to the Act rather than to the Code.

a color to the body, such as lipstick, rouge and eye make-up colors, whereas the Amendments require listing and certification only of the color ingredient added to the product;

(2) Apply such listing and certification requirements to non-color ingredients of finished cosmetic products, which the Regulations call "diluents", whereas the Amendments make no provision for listing diluents and merely authorize certification of the color ingredient, with safe diluents or without diluents;

(3) Change and limit the statutory exemption for hair dye products, in addition to applying such listing and certification requirements to such products, whereas the Amendments do not affect the exemption for such products; and

(4) Grant FDA inspectors access to cosmetic formulae, a subject not even mentioned in the Amendments.

Proceedings Below.

Respondents sued in the United States District Court for the Southern District of New York for a declaratory judgment that each of such four provisions of the Regulations are invalid as in excess of petitioners' statutory authority, and for an injunction against enforcement.*

Petitioners moved to dismiss on numerous technical and procedural grounds, principally for failure "to state a case of actual controversy * * * because of the absence of any threatened or attempted enforcement of the regulations" (R. 69). Respondents moved for summary judgment.

The District Court found "compelling reasons for assuming jurisdiction and determining in this action the validity of the challenged regulations" (R. 73), but denied

* Jurisdiction was invoked under 28 U.S.C. §1331(a), and the action was alleged to be authorized by the Declaratory Judgments Act, 28 U.S.C. §§2201, 2202 and Section 10 of the Administrative Procedure Act, 5 U.S.C. §1009, later recodified as 5 U.S.C. §§701-706 (R. 7).

summary judgment, concluding that "testimony relative to legislative intent" was desirable (R. 75).

After extensive discovery, petitioners made a renewed motion to dismiss based on *Abbott Laboratories* v. *Celebrezze*, 352 F. 2d 286 (3d Cir. 1965), *cert. granted*, 383 U. S. 924 (1966), No. 39, and *The Danville Tobacco Association* v. *Freeman*, 351 F. 2d 832 (D. C. Cir. 1965), "on the grounds that (a) the complaint fails to set forth a justiciable controversy and (b) this is an unconsented suit against the United States" (R. 76). The District Court, finding the situation "significantly different" from *Abbott Laboratories* (R. 50), denied the motion. The case was certified for interlocutory appeal and appeal was allowed (R. 52, 117).

The Court of Appeals, though finding *Abbott Laboratories* "not distinguishable on any satisfying basis" (R. 135), held that the issues framed as to the three provisions involved in the first three counts of the complaint,—which, as above noted, extended the Amendments' listing and certification requirements from color ingredients to the finished product itself, including hair dyes, and to its non-color ingredients,—were "suitable for immediate judicial resolution" (R. 136). However, as to the fourth count,—relating to access to cosmetic formulae,—the Court of Appeals concluded that injury to respondents was "too remote for declaratory relief" (R. 137), and reversed.*

Since it was assumed the identical test of reviewability applied to all four challenged provisions of the Regulations, they were always considered collectively below. The Court of Appeals, without the issue having been briefed or argued, made the distinction as to the fourth count,—the issued presented by No. 336.

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* The Government's claim that this is an uncontested suit against the United States was rejected as "plainly foreclosed by Supreme Court decisions" (R. 129, fn. 6) and has been abandoned.

Background of the Regulations.

To make it appear the challenged provisions of the Regulations impose "no present obligation" on the cosmetic industry, that "respondents' injury is distant and speculative" (Br. 17) and that the case merely presents differences of "interpretation" or legal opinion, petitioners present a beclouded description of the Regulations and their impact. A fair description of the Regulations is prerequisite to the issue of judicial reviewability. Also essential to full understanding is an analysis of the statutory scheme and the background and legislative history of the Amendments, as well as a description of their provisions.

These will show that the Regulations apply forthwith and have a direct and immediate impact on the cosmetic industry, and that the issue is not one of mere "interpretation" but of administrative usurpation of power and authority beyond and radically different from that granted by the Amendments. While this is apparent by merely comparing the Regulations with the Amendments, perhaps aided by their legislative history, it is buttressed by the fact that each challenged power FDA took by the Regulations had been sought from Congress and withheld.

The Statutory Scheme.

The Act,—which imposes severe civil and criminal penalties for sale of "adulterated" articles of food, drugs and cosmetics,—places finished products and their ingredients in three carefully delineated categories:

(1) The first is *finished products* [*food, drugs* (other than "new drugs,") and *cosmetics*], which do not require prior FDA approval or premarketing clearance, but as to which after sale the manufacturer and seller, and the product itself, are subject to penalties if the product is "deemed to be adulterated", that is, "contains any poisonous or

deleterious substance which may render it injurious to users" (§601 (a)). Except as to "new drugs", finished products need not be cleared before marketing. Congress, however, specifically exempted from coverage, *even after sale*, hair dyes (other than eye-lash or eyebrow dyes), if labelled as required by the Act (§601 (a)).

(2) The second is a *"new drug"*, the only finished product which requires prior FDA approval or premarketing clearance (§505 (a)).

(3) The third is *specific ingredients* in the product. As to food, prior clearance is required for various added ingredients called "food additives";—a requirement imposed by the "Food Additives Amendment of 1958" (72 Stat. 1784 (§409)).

As to food, drugs and cosmetics, prior FDA clearance, as noted above, is also required for the color ingredient added to the product and called a "color additive". Such prior clearance is accomplished by requiring (1) pretesting of the color to establish safety; (ii) petitioning FDA for listing the color in a regulation, which states the specifications for the color; and (iii) FDA certification of batches of the color to establish compliance with its specifications (§706 (b)(c)), unless the color is exempted from certification.

The exemption for finished hair dye products was also implemented in Section 601(e) to exempt the color ingredient in the hair dye.

The Act grants FDA certain factory inspection authority. FDA agents may inspect "processes" of prescription drugs only, not cosmetics, food and non-prescription drugs (§704(a)).

Background of the Color Additive Amendments.

(1) The Act Prior to the Amendments.

A color ingredient is added to food, drugs and cosmetics, either to impart color to the product or to enable the product to apply color to the body. The color ingredient may be a dye, pigment or some other substance (R. 7-8, 103). The term "color additive" signifies that the color ingredient has been added to the product (R. 7).

Color additives may be colors derived from natural sources, known as "natural colors", or be made by a process of synthesis, known as "synthetic colors". Synthetic colors became generally used as the color additive in food, drugs and cosmetics, particularly chemical compounds of a coal-tar origin known as "coal-tar colors" (R. 8, 103).

Under the 1938 Federal Food, Drug and Cosmetic Act (52 Stat. 1040),—the first to regulate cosmetics,—only coal-tar colors were required to be listed and certified* (R. 9-10).

FDA regulations defined coal-tar colors and prescribed the requirements for listing, involving pretesting and scientific investigations, and for certification of batches of coal-tar colors. FDA regulations listed a total of 118 coal-tar colors, with specifications for the color. (21 C.F.R. (1949 ed.) §135, pp. 113-128.) There was never a listing of the finished cosmetic product itself or its numerous non-color ingredients. Nor was there ever listing of a hair dye product or its color ingredient, or disclosure of the formula of a cosmetic product (R. 105-6).

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*"SEC. 604. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents."

Comparable provisions of the 1938 Act applied to food (§§402 (c), 406(b)) and drugs (§§501(a)(4), 504).

(2) Emergency Which Resulted in Enactment of the Color Additive Amendments as a Relief Measure for the Color, Food, Drug and Cosmetic Industries—The "Harmless *per se*" Principle *versus* the "Safe-for-Use" Principle.

In 1952, FDA determined that the statutory provisions "for the listing of coal-tar colors which are *harmless and suitable for use*"* in food, drugs and cosmetics meant the color had to be entirely lacking in toxicity; that "harmless" was used in an absolute sense; that if a coal-tar color in any quantity, regardless of how large or concentrated, could produce any toxicity, it could not be listed as "harmless and suitable for use" even if harmless as to a particular use in a food, drug or cosmetic, or in the tolerance or quantities involved in such use; and that FDA could not establish tolerances for the use of coal-tar colors in the finished product. This is called the "harmless *per se* principle" (R. 10-11).

Prior to 1952 and since 1906, the applicable test was whether the color was harmless in the actual quantity used or in its particular use or application. This is called the "safe-for-use" principle (R. 11).

Application of the "harmless *per se*" principle was sustained in *Flemming* v. *Florida Citrus Exchange,* 358 U. S. 153 (1958). As a consequence, substantially all coal-tar colors had to be delisted, threatening removal from the market of articles of food, drugs and cosmetics which contained such colors, which had received wide consumer acceptance and which experience had established were safe in their particular uses. Remedial legislation was urgently needed to sanction the "safe-for-use" principle and prevent needless destruction of the color, food, drug and cosmetic industries (R. 10-11, 111-2).

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* Unless otherwise noted, italics throughout have been supplied.

Accordingly, FDA, in close asssociation with the affected industries, prepared the bill which became the Color Additive Amendments of 1960 (R. 11).

(3) The Legislative History of the Color Additive Amendments—Their Two-fold Purpose.

The Amendments' primary purpose was to counteract *Flemming* v. *Florida Citrus Exchange* and enable FDA to establish quantity or tolerance limitations for colors in particular products. FDA decided also to obtain extension of listing and certification from coal-tar colors alone to all colors, natural and synthetic. This two-fold purpose is clear from the legislative history.

It was stated in the House Report on the Amendments, which summarized the "principal reasons which give rise to the need for this legislation" (R. 109-113, 12):

> "1. The law with respect to coal-tar colors * * * does not allow the Secretary of Health, Education, and Welfare *to list a color for safe use* under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. * * * *the Secretary must ban the use of such a color completely, as not being 'harmless,' if it is found to be toxic in the laboratory when fed to animals in some concentrations, even though its actual level and manner of use may be completely safe.*"
>
> * * * * * *
>
> "3. There is a need for making applicable to *all color uses* and *all types of color*—whether they be *coal-tar colors or others*—the same pretesting requirements and, where necessary for the protection of *color users* and consumers, the same requirements for certification of *colors* to assure their purity and identity with those listed as safe."
>
> * * * * * *

> "The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting the listing of *colors* under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, * * *"

There is not a suggestion in the entire legislative history* of any intent to extend pretesting, listing and certification from color ingredients alone to finished cosmetic products, and thereby establish an entirely new system of premarketing clearance for such products or their noncolor ingredients; or to eliminate, limit or modify the statutory exemption for hair dye products; or to grant FDA access to formulae of cosmetics. Clearly, such major innovations would have been noted during the protracted legislative history. *Ozawa* v. *United States*, 260 U. S. 178, 194 (1922).

On the contrary, it was emphasized that the Bill did not require premarketing clearance; a strong recommendation that such requirement again be considered was not adopted.**

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* See "Color Additives, Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives", 86th Cong., 2 Sess., on H. R. 7624 and S. 2197, pp. 15-6 ("1960 Hearings"). The twofold purpose was also emphasized in testimony before the Committee (pp. 39-40), in statements by Committee members (pp. 1-2) and in discussion in the House (106 Cong. Rec. 14349, 14350, June 25, 1960).

** Congresswoman Sullivan, who had sponsored legislation for premarketing clearance of cosmetics, stated that such "cosmetic bills have been pending before you for some years," that the color additives bill would "establish, for the first time, a basis for clearing in advance the safety of non-coal-tar colors used in cosmetics," and further stated:

> "But what of all of the other ingredients in cosmetics? If we are going to require manufacturers to prove the safety

The Provisions of the Color Additive Amendments.

The Amendments accomplished the two-fold purpose in the following manner:

(1) The requirement for listing and certification was extended from coal-tar colors to all colors by changing "coal-tar color", used in the 1938 Act, to "color additive". The term "color additive", to designate color ingredients added to food, drugs and cosmetics, evolved from "food additive" adopted in the 1958 Amendments to designate ingredients added to food (R. 112). As already noted, FDA had defined coal-tar color by regulation. This definition was carried into the Act, except that "coal-tar color" was changed to "color additive" and appropriate language was used to cover the natural colors. (R. 103, 14). (§201(t), App. Pet. Br. 24-5).

(2) The second purpose, authorizing FDA to list colors on the basis of quantity limitation and a specific product, was covered by Section 706(b) entitled "Listing of Colors", which authorized "tolerance limitations, as to the maximum quantity or quantities which may be used", and other conditions of use of the color added to the food, drug or cosmetic.

The Amendments did not change the statutory exemptions for hair dye products (§601(a))* or affect or even mention factory inspection.

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of their non-coal-tar color additives in cosmetics, *why not in the same legislation and at the same time and under the same standards require the manufacturer to establish the safety of all ingredients in his cosmetics product?*" (1960 Hearings, pp. 113-4.)

* The actual amendments, prior to collation into the Act, underscored Congressional intent not to affect the hair dye exemption, by describing Section 601(e) as "relating to cosmetics, other than hair dyes". (P. L. 86-618, 74 Stat. 397, 398, §102(c) (1)). The House Report explained that the Amendments contained such hair dye exception "since coal-tar hair dyes are not covered by section 601(e) of the act" (H. Rpt. No. 1761, dated June 7, 1960, U. S. Code, Cong. Adm. News (1960), Vol. 2, p. 2906).

The Provisions of the Color Additives Regulations.

The Regulations accomplish the purpose of the Amendments by prescribing the procedure for listing all colors, coal-tar and natural, and for certification or exemption from certification, and by covering the tests "applicable to show whether or not the color additive will be safe for its intended use" in the article of food, drug or cosmetic, including such matters as "proposed tolerances" (§8.4(c), App. pp. 2a-3a, *infra*). However, the Regulations far exceed both the language and purpose of the Amendments in four areas. As to each area FDA had sought legislation to obtain the desired power, but Congress refrained from the grant. Finally, FDA just took the power, as follows:

(1) FDA's Assumption of Power to Require Premarketing Clearance of Finished Cosmetic Products.

FDA, in defining "color additives" in the Regulations, inserted one brief sentence which subjects substantially the entire cosmetic industry to premarketing clearance of finished cosmetic products (§8.1(f), App. Pet. Br. 37):

> "Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are 'color additives'."

FDA's release of June 22, 1963, announcing the Regulations, described them as imposing a "new requirement" and stated (R. 106):

> "Under the new regulations, FDA *will require that an entire product*—not just the color ingredient —be shown by the manufacturer to be safe before it is released for sale."

Petitioners acknowledge that the Regulations apply the listing and certification requirements not only to the color ingredient but also to the finished cosmetic product, and that "the sale of any finished color-imparting cosmetic product [is prohibited] *if that finished product is not itself listed as safe and certified or exempted*" (Br. 12).

FDA, to minimize the Regulations' scope, asserts FDA "does not require pre-marketing licensing" "for cosmetics which do not impart color to the human body" (Br. 5, fn. 4). However, it is conceded the Regulations impose pre-marketing clearance for lipstick, rouge, eye makeup colors, all hair dyes and hair coloring products, leg applications, pancake makeup, suntan lotions, nail polish and nail enamel and innumerable other cosmetics. Since "color" is defined to include "white" (§8.1(f)), FDA agreed the regulations even embrace shaving creams, baby oils and like products. Ellenbogen of FDA was unable to specify any cosmetic not covered by the Regulations; he did not "know of any", could not "name any offhand", and was "not sure" whether all toothpastes were covered (R. 88-89).*

However, regardless of whether certain cosmetics are reached, it suffices as to the issue of excess of statutory authority that the Regulations impose premarketing clearance for the cosmetics above mentioned, which are manufactured by respondents whose businesses are drastically affected thereby.

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* Petitioners err in stating there is dispute as to the Regulations' coverage and that respondents have claimed they "establish a pre-marketing licensing system for *all* cosmetic products and ingredients," whereas FDA claims the Regulations apply "only to those cosmetics that impart color to the human body" (Br. 5, fn. 4). Petitioners have never claimed the Regulations specifically apply to "all cosmetic products." The complaint recognizes they apply only to "cosmetics intended for applying color to the human body" (R. 20, 42). Petitioners have merely shown that by defining color to include white, the reach of the Regulations became extremely extensive. This is confirmed by FDA's difficulty in specifying cosmetics not covered by the Regulations.

(2) FDA's Assumption of Power to Require Premarketing Clearance of Non-Color Cosmetic Ingredients.

The Regulations catch substantially all non-color cosmetic ingredients by providing that "color additive" "includes all diluents" (§8.1(f)), defined to mean substantially all non-color cosmetic ingredients (§8.1(m), App. Pet. Br. 37).

A diluent is an inert substance used to dilute dyes or pigments, which are generally stronger than needed to impart color to the product (R. 104-5). The term "diluent", as already noted (p. 8, fn., *supra*), was used in the 1938 Act when its listing and certification requirements concededly applied only to coal-tar colors. There was no requirement for listing diluents; the Act merely provided that a coal-tar color in food, drugs or cosmetics could be certified "with or without harmless diluents" (§604; see p. 8, fn., *supra*). This pattern was preserved by the Amendments which nowhere suggest diluents must be listed, but merely authorize color additives to be *certified* for use "in or on food or drugs or cosmetics" "with safe diluents, or without diluents" (§706(a)(c)).

Since the primary purpose of the non-color ingredients is not to dilute the color, but to serve as emollients, stabilizing, emulsifying, imparting an odor, and the like, they are not, and have never been considered, diluents. Neither listing nor certification of such non-color ingredients was ever required (R. 104, 28-9).

The Amendments made no change as to diluents. The legislative history nowhere suggests that non-color ingredients be deemed diluents or that diluents be listed.

By defining "color additive" to include "all diluents," and defining "diluents" to mean substantially all non-color cosmetic ingredients, FDA has assumed the power to require pretesting, *listing* and certification of substantially

all ingredients in all cosmetics (R. 28-9). Miller of FDA conceded the Regulations define "diluent" "to include every ingredient of every cosmetic product that contains a color" (R. 85).

(3) FDA's Repeal and Limitation of the Statutory Hair Dye Exemption.

The Regulations substantially repeal the statutory hair dye exemption in two ways:

(i) The definition of color additive, embracing any cosmetic "intended for coloring the human body" (§8.1(f)), includes all hair dye products, and thereby requires for them the same premarketing clearance imposed for lipstick, rouge and the like.

(ii) The Regulations seek to repeal the statutory exemption for hair dye products and their color ingredients (§8.1(u), App. Pet. Br. 37-8).

FDA's intent to rewrite the Act is manifest from its release of June 22, 1963, which stated that the statutory hair dye exemption offered insufficient protection; that "the purpose of the new regulation is to close this gap", and that hair dyes which do not cause a reaction with the prescribed test for skin sensitivity "*must now be demonstrated to be safe before they can be marketed*" (R. 106).

Equally candid is the FDA release of October 3, 1963, which describes the Regulations as "*limiting* the exemption for hair dyes under the Federal Food, Drug, and Cosmetic Act" (R. 108).

FDA cannot even purport to justify repealing or limiting the hair dye exemption by anything in the Amendments, which, as already noted, did not even touch the Act's hair dye provisions, except to reaffirm the statutory exemption.

Substantially the entire cosmetic industry in the United States is presently subject to the Act's criminal and civil sanctions, including multiple seizure of substantially all its products, for non-compliance with the first three challenged provisions of the Regulations. FDA has indicated it would defer criminal and civil enforcement proceedings during pendency of this action (R. 90).

(4) FDA's Assumption of Power to Require "Free Access" to the Processes and Formulae of Cosmetics.

The Regulations in effect grant FDA access to cosmetic processes and formulae by providing for suspension of certification for refusal of "free access to all manufacturing facilities, *processes*, and *formulae* involved in the manufacture of color additives" (§8.28(a), App. Pet. Br. 38), defined to include substantially all finished cosmetic products. Suspension of certification prevents sale of the product and will, as the accompanying FDA release stated, "in effect ban it from the market" (R. 106-7).

Here, also, FDA cannot justify extension of statutory inspection power by anything in the Amendments, which did not touch the factory inspection provisions.

Since reviewability of the "free access" provision is a separate issue presented by No. 336, the background of such provision and the manner whereby FDA took power long desired by it, and long withheld by Congress, will be separately developed (pp. 18-21, *infra*).

Congressional Refusal to Grant FDA the Power Taken by the Color Additives Regulations.

(1) The First Three Challenged Provisions of the Regulations, Reviewability of Which Is Presented By No. 438.

Pertinent to FDA's excesses of statutory authority is the fact, already alluded to, that FDA itself sponsored

legislation to obtain the very powers taken by the Regulations. The bills were numerous.*

One example, H. R. 11582, introduced May 3, 1962, should suffice (R. 114-5). Title I, entitled "PREMARKETING CLEARANCE OF COSMETICS FOR SAFETY," contains provisions limited to "New Cosmetics" which parallel the provisions for approval of "new drugs." They require a "new cosmetic" application, accompanied by "full reports of investigations" "to show whether or not such cosmetic is safe for use", and "a full statement of the composition of such cosmetic" (§605(b)(1)(3)). A cosmetic is "deemed unsafe" and therefore may not be sold unless the application has been approved (§605(a)).

Section 103, entitled "REPEAL OF SPECIAL EXEMPTIONS FOR HAIR DYES," contains provisions deleting the Act's hair dye exemption (R. 116).

Comparable legislation was sought the following year, including another FDA sponsored bill.**

(2) The "Free Access" Provision of the Regulations, Reviewability of Which is Presented By No. 336.

The Act's original factory inspection provision authorized FDA, after "obtaining permission of the owner," to enter factories manufacturing food, drugs, devices and cosmetics and inspect "all pertinent equipment, finished and unfinished materials, containers, and labeling therein" (52 Stat. 1057, §704). The right to inspect processes and formulae was not granted.

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* Three such bills are annexed as exhibits to an affidavit in behalf of respondents (R. 88). In preparing the Appendix for the Court of Appeals, petitioners failed to reproduce these exhibits, and hence they are not included in the printed record before this Court.

** H. R. 1235, introduced January 9, 1963, 88th Cong., 1st Sess., and H. R. 6788, introduced June 4, 1963, 88th Cong., 1st Sess.

In 1953, following *United States* v. *Cardiff*, 344 U. S. 174 (1952), the Act was amended to eliminate the permission requirement (67 Stat. 477). But inspection of processes and formulae was still not granted. According to William W. Goodrich, counsel for petitioners in both Nos. 336 and 438:

> "The managers of the bill expressed their opinions that it would not be a reasonable inspection to demand access to formula files * * *."*

FDA subsequently sponsored the "Drug and Factory Inspection Amendments of 1962" (H. R. 11581, 87th Cong., 2d Sess.), whereby it sought access to factories "in which food, drugs, devices, or cosmetics are manufactured," and to inspect "all things therein (including * * * processes * * *)". The stated purpose was to "strengthen existing inspection authority" to grant FDA access to "processes" of food, drugs, devices and cosmetics**.

The Secretary testified that FDA inspectors "are refused access to formula files" and that (1962 Hearings, pp. 67, 68):

> "H. R. 11581 would remedy this problem by granting the Food and Drug Administration authority to make complete inspection of all establishments producing foods, drugs, devices, or cosmetics. This

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* Paper delivered by William W. Goodrich, Assistant General Counsel, FDA, before American Bar Association's Food, Drug & Cosmetic Law Division, Aug. 8, 1962, published in The Business Lawyer, Vol. XVIII, No. 1, Nov. 1962; pp. 203, 204.

** Drug Industry Act of 1962, Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 87th Cong., 2d Sess., held June 19, 20, 21, 22; Aug. 20, 21, 22, 23, 1962 on H. R. 11581 and H. R. 11582 (the "1962 Hearings"), pp. 11, 30.

provision would allow inspection of all * * * processes, * * *."

He further testified as to his existing authority (1962 Hearings, p. 72):

"The Chairman: Are you authorized to look at the formula files?

"Secretary Ribicoff: We are not."

Industry opposition came not only from the cosmetic industry but from the food industry, which was most concerned at the threatened exposure of vital trade secrets.*

Congress enacted the requested "free access" to processes and formulae, but only as to factories "in which prescription drugs are manufactured" (§704 (a), 76 Stat. 792). It withheld the authority as to foods, non-prescription drugs, devices and cosmetics. The law, as passed October 10, 1962, dropped "Factory Inspection" from its title, and was called "Drug Amendments of 1962".**

To underscore the Amendments' inapplicability to cosmetics, Congress specifically provided they "shall not apply to any cosmetic unless such cosmetic is also a drug or device or component thereof." (§509, 76 Stat. 791)

FDA Counsel Goodrich stated that the "need" for FDA access to formulae of all products was so "real" that "we will continue with all our abilities to urge the Congress to meet the need."***

Accordingly, in 1963 FDA sponsored H. R. 6788,† Section 101 of which was captioned "EXTENSION OF PRESCRIP-

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* See particularly a statement by the National Canners Association (1962 Hearings, p. 137).

** §704(a), as amended by Pub. L. 87-781, Oct. 10, 1962, 76 Stat. 792, §201. These amendments and certain regulations thereunder as to labeling are the ones involved in *Abbott Laboratories* v. *Celebrezze* (No. 39).

*** Business Lawyer, Vol. XVIII, Nov. 1962, p. 207.

† See p. 18 fn., *supra*.

TION DRUG INSPECTION AUTHORITY TO OTHER DRUGS, FOOD, COSMETICS, AND DEVICES". The Secretary's transmittal letter, dated May 29, 1963, stated that "The enclosed bill would * * * extend the inspection authority presently applicable only to prescription drugs to all other products covered by the Food, Drug, and Cosmetic Act." The requested authority was again withheld.

Subsequently, FDA, by the challenged regulation, simply took the power to obtain "free access" to all cosmetic "processes, and formulae." Its accompanying release warned that refusal of such access "*may*" cause FDA to refuse to certify the cosmetic and "thus *in effect ban it from the market*" (R. 106-7). FDA use of "may" rather than "will", which so strongly influenced the Court of Appeals to regard the possibility of unlawful injury as too remote for declaratory relief (R. 137), can hardly soften the impact on the cosmetic industry of the power it illegally took or its warning to industry.

The Finality and Mandatory Nature of the Regulations.

The District Court determined the Regulations are "final" (R. 49, 50). Below petitioners also called them "final regulations" (Br. CA, p. 8), though they now suggest lack of finality (Br. 17).

The Regulations were promulgated pursuant to the "Rule making" procedure of the Administrative Procedure Act (the "APA"), 5 U. S. C. §553. FDA first gave "General notice of proposed rule making * * * published in the Federal Register" January 24, 1961* (26 Fed. Reg. 679) (§553(b)). It afforded "interested persons opportunity to participate in the rule making through submission of written data"* (§553(c)) and published the final

* Petitioners advance the lame excuse,—not suggested until this Court,—that they followed APA's formal rule making pro-

Regulations June 22, 1963 (28 Fed. Reg. 6439, 21 C. F. R. §§8.1 *et seq.*). Accordingly, "The process of rulemaking was complete. It was final agency action" and the Regulations "now operate to control the business affairs" of respondents. (*United States* v. *Storer Broadcasting Co.*, 351 U. S. 192, 198, 199 (1956)).

The Regulations state that "This *order* shall become effective" on publication in the Federal Register, except that "§8.30 [as to certain diluents] shall become effective one year after publication."

An FDA release stated its "regulation limiting the exemption for hair dyes * * * *applies immediately* only to new hair dye formulations coming on the market * * *. Products currently being marketed *will not be affected* until June 22, 1965 * * *" (R. 108).

A mere "difference of view" or announcement of what FDA "believes," as petitioners characterize the Regulations (Br. 17, 8), would not be called an order, or provide for an effective date or have three separate effective dates. This alone shows the Regulations are meant to have the force of law. (*Cf. Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407, 420-421 (1942).)

FDA stressed their mandatory nature. Its formal release, describing the applicable provision as a "new require-

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cedure because otherwise "it would not have the benefit of the views of the affected industry" (Br. 15). This argument is patently specious. It is common practice for FDA informally to obtain industry comments on any proposed action, and this could be done without the formal rule making procedure.

Furthermore, the notice of the proposed rule making did not even contain the challenged provision defining "color additives" to include lipstick, rouge and other finished cosmetic products so that industry was not even apprised of FDA's intent to require the listing and certification of finished cosmetic products or to obtain access to cosmetic formulae.

ment," stated that before the Regulations "only color • • • ingredients had been subject to the requirement for premarketing proof of safety," whereas now "FDA *will require*" premarketing clearance for the "entire [cosmetic] product—not just the color ingredient" (R. 106). Referring to an alleged loophole in the Act as to hair dyes,— the FDA release stated the Regulations "close the gap" and hair dye products "*must* now be demonstrated to be safe before they can be marketed" (R. 106).

FDA's answers to interrogatories state: "Any cosmetic intended to impart color to the human body *would have to be listed*" (R. 83). Deputy FDA Commissioner Harvey agreed the Regulations "*require* listing" of substantially all cosmetics (R. 83). This hardly suggests the Regulations impose "no present obligation" (Br. 17).

The Burdens Imposed on the Cosmetic Industry by the Regulations.

The Regulations, to the extent they exceed the statutory authority, have direct and immediate impact on respondents, impose tremendous burdens not authorized by the statute and cause respondents irreparable harm (R. 21-2, 29-30, 37, 41, 99-102).

(1) The Regulations require a separate petition for listing every cosmetic which imparts color to the body, as well as their non-color ingredients (§§8.1(f)(m), 8.4(c)). For respondent Kolmar Laboratories, Inc. ("Kolmar") alone,—a private brand manufacturer which makes over 2,700 different formulae and cosmetics which color the body,—the listing fees, at $2,600 a cosmetic (§8.50(c)), would be approximately $7,000,000. Since Kolmar uses 264 non-color ingredients in its finished cosmetic products, which the Regulations now call "diluents", it must now

also obtain separate listing* for such ingredients (§8.50(j)) (R. 99-100, 22).

(2) Each listing petition must be supported by extensive physical and chemical tests (§8.4(c), App. 2a-3a, *infra*), as alleged in the complaint and described in a Kolmar affidavit (R. 21-2, 99-102), estimated to cost Kolmar alone between $8,100,000 and $42,000,000 (R. 101). FDA estimated 20 years to complete the retesting program for colors (106 Cong. Rec. 14350, June 25, 1960).**

(3) Batches of all cosmetics must be inspected and certified, unless exempt from certification, with a separate fee for each certification (§8.50(j)). Kolmar's estimated cost of a year's certification fees is approximately $750,000 (R. 101).***

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* While FDA has listed some "diluents" on its own initiative, this does not materially reduce listing fees in view of the hundreds of cosmetic ingredients still unlisted. FDA has recognized that "no final cosmetic product would be prepared from the few diluents" listed by FDA on its own initiative. ("Pretesting of Cosmetics for Consumer Protection" by Miller and Kline, FDA, presented before Tenth Annual Society of Cosmetic Chemists Seminar, Sept. 24-25, 1963.)

** Harvey testified that the testing and detailed information would "be required in connection with applications for listing rouge, leg applications, pancake makeup," and all other finished cosmetic products which color the body (R. 84).

*** The cost of compliance with the Regulations is so incredibly staggering that both courts below assumed the estimates had to be exaggerated (R. 72, 127, fn. 5). Petitioners now argue that compliance costs will not be as high as respondents indicate because the $2,600 listing fee is a deposit to cover processing costs and "any excesses may be refunded", though such refund is in fact rare.

Petitioners further state there is no requirement that each different shade of lipstick be listed, and that one listing covers all lipsticks produced by a cosmetic manufacturer. (Br. 19, fn. 8). This, however, is contrary to Harvey's testimony that each separate shade of lipstick, or any other cosmetic having varied formulae, would require separate listing (Tr. Dep. 1/21/65, p. 454). Also though the Kolmar affidavit, which states that its 2,700 different finished cosmetic products that color the body must each be listed,

(4) Each manufacturer must maintain complete and separate detailed records (§8.26, App. 3a, *infra*), which for Kolmar would require five additional employees (R. 101-2).

(5) The new requirement for listing finished cosmetic products and their non-color ingredients, with consequent publication of formulae and processes in the Federal Register, would permit appropriation of secret cosmetic formulae by competitors and destroy incentive for costly research and development of new cosmetics (R. 102, 46-7).

The District Court stated in its first opinion that "there can be little doubt but that the added recordskeeping and laboratory testing costs in themselves will be extremely burdensome for all of the plaintiffs", but that aside from the "costs of compliance" "the impact of the regulations on plaintiffs' present methods of doing business will be substantial and give rise almost certainly to potentially greater expenses" (R. 72). It also noted the fact that granting "access to all formulae and processes will have an immediate adverse effect upon further research and development of new products" (R. 72). Its second opinion reaffirmed that "irreparable harm would attach to plaintiffs" (R. 50).

The Court of Appeals noted the allegations of the complaint and the supporting affidavit which described the burdensome impact of the Regulations and the hardship they imposed on the cosmetic industry (R. 127).

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was made March 25, 1964 (R. 102), none of petitioners' responsive affidavits ever denied such separate listings are required. On the contrary, Harvey testified that if Kolmar's 2,700 products each had a different formula, as the Kircher affidavit states, each would have to be separately listed, and a separate fee of $2,600 paid (Tr. Dep. 1/21/65, p. 465). In any event, the burdens and hardship of the Reglations are tremendous, even if Kolmar's estimate of over $50,000,000 as its cost of compliance should be pessimistic.

Summary of Argument.

1. The question of reviewability must be determined on the allegations of the complaint since the issue is presented by motion to dismiss. The essence of the complaint is that the Regulations exceed the Commissioner's statutory authority and arrogate to him broad powers not granted by statute.

The Regulations are not merely "interpretative" but in effect constitute "legislating" by FDA to obtain the very authority Congress had refused to legislate. However, their label is a matter of form and terminology unrelated to their substance, reach and impact.

There is inherent equity jurisdiction in federal courts to determine the limits of an agency's statutory authority. An actual controversy is presented involving clearcut issues of law and statutory construction appropriate for judicial resolution through injunction and declaratory judgment.

Violation entails severe criminal, civil and multiple seizure penalties. Respondents are not required either to act at their peril and risk such penalties if not sustained, or to comply with regulations deemed illegal and abandon their rights for fear of penalties.

The purpose of the Declaratory Judgments Act was avoidance of such dilemma; it provided an added remedy to the pre-enforcement review available in equity.

Respondents are persons suffering a legal wrong because of final agency action in excess of statutory jurisdiction. Therefore, additional ground for review is authorized by the APA.

Under these circumstances, the complaint presents an actual case and controversy appropriate for judicial resolution in advance of enforcement.

2. The Act contains nothing on its face to establish Congressional intent to withhold prior judicial review or to deny the general review jurisdiction vested in federal courts. The Act provides for a special statutory procedure and direct appeal to a court of appeals, which must affirm agency findings based on substantial evidence. This procedure applies to regulations issued under specified sections of the Act which involve technical matters within the agency's expertise. It is not intended to be exclusive or to establish Congressional intent by implication that other regulations are not reviewable in equity or by declaratory judgment..

Congressional intent to preserve pre-enforcement judicial review was emphasized by the saving clause in the Act which provides that such special statutory procedure is in addition to and not in substitution for any other remedies provided by law. The saving clause is not limited to those regulations to which the special statutory procedure applies. The House Report on the Act emphasizes the right to proceed in equity to enjoin a regulation and to initiate a declaratory judgment proceeding.

3. The Regulations are final, mandatory regulations promulgated pursuant to APA's formal rule-making procedure and impose present obligations on respondents having the force of law. The Regulations apply immediately to finished cosmetic products which impart color to the body, as well as to non-color ingredients and hair dye products exempted from the Act's coverage. There is no basis for petitioners' contention that the provisions of the Regulations requiring the listing and certification of finished cosmetic products do not apply until a future contingent date, after listing and certification of the color ingredient. Accordingly, petitioners' position that the Regulations

impose "no present obligation" and that respondents' injury is "distant and speculative" is groundless.

4. Nor is there basis to petitioners' position that challenge of validity should be by the special statutory procedure. That procedure is limited to factual matters within the agency's special competence. As FDA itself has ruled, its authority to promulgate a regulation presents a question of law which cannot be resolved in an administrative hearing.

The determination of excess of statutory authority does not involve taking evidence, but analysis and interpretation of the Act and its legislative history and comparison with the Regulations. This is traditionally a judicial function appropriate to a court of equity.

5. The Court of Appeals erred in holding the provision as to free access to cosmetic formulae not subject to prior judicial review. The fact that the dilemma of complying with an illegal regulation or risking penalties of non-compliance is not actually faced until an FDA inspector seeks free access against a particular respondent is not sufficient to preclude judicial review. Equity has jurisdiction to anticipate and prevent impending injury by unlawful action. Relief may be granted against excess of statutory authority though not presently directed against a particular party.

The "free access" provision does not stand alone. It is interrelated with the other three challenged provisions as elements of a common plan of governmental regulation, and all four should be reviewed together.

6. *Abbott Laboratories* (No. 39) presents a different situation. Affirmance there would not control the case at bar because of the substantially different nature of the Color Additives Regulations.

The four challenged provisions of the Regulations are clearly reviewable by injunction, declaratory judgment and under the APA. Petitioners should not be permitted to hold an entire industry at hazard by preventing immediate and direct test of the validity of the Regulations. The case should be remanded to the District Court for decision on the merits as to the four challenged provisions.

Argument.

I.

The Regulations are reviewable in this action.

A basic defect in petitioners' position* is its misconception of the complaint, described as merely seeking a declaration that the Regulations are "an unauthorized interpretation" of the Amendments (Br. 5). The complaint, however, alleges that by final mandatory regulation, effective immediately, FDA imposed substantial and highly burdensome obligations on the cosmetic industry "in excess of the statutory jurisdiction, authority and limitations of the defendants" (R. 2, 20, 29, 36, 40), and that "the Commissioner arrogated to himself a power and authority not granted" by Congress (R. 20, 28, 35, ~~39~~-40) in defiance of specific Congressional action withholding the power. Since the reviewability issue is presented on a motion to dismiss,

* Petitioners appear to incorporate the arguments in the Government's brief in *Abbott Laboratories*, No. 39 (Br. 13), without indicating which portions apply to the Color Additives Regulations. We assume that that brief (the "Abb. Br.") will be adequately replied to by petitioners in that case. Accordingly, respondents will make only occasional reference thereto.

such allegations must be taken as true.* *Joint Anti-Fascist Refugee Committee* v. *McGrath*, 341 U. S. 123, 126 (1951); *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407, 414 (1942); *Stark* v. *Wickard*, 321 U. S. 288, 305, 311 (1944).

A. The Regulations Are Not "Interpretative" But Are Legislative or Substantive Regulations Which Purport to Have the Force of Law. However, Even If Deemed Interpretative, They Are Subject to Pre-Enforcement Judicial Review.

(1) It is petitioners' basic contention that the Regulations, entitled, "Definitions * * * and Interpretative Regulations," are merely "interpretative"** and therefore, not subject to pre-enforcement judical review,—a position the District Court stated "smacks of hypertechnicality" (R. 49). The Court of Appeals saw "little profit in debating the point * * * whether the Regulations are 'interpretative' or 'legislative'," and held "the interpretative character of a regulation does not necessarily make it unripe for review" (R. 134-5).

Petitioners' *Abbott Laboratories* brief describes interpretative regulations as voluntary guides to industry. Examples there given relate to "use in drug manufacture of ox bile from condemned livers of slaughtered animals" (21 C.F.R. 3.16), and "the quantity of egg which must be

* On the renewed motion to dismiss the District Court, in view of the extensive discovery after denial of the first motion, had before it substantial evidence to support the allegations, as well as the legislative history. These led it to observe that the Regulations "rather markedly depart from what preliminarily appears to be the plain legislative authority conferred by Congress" (R.51).

** Interpretative regulations are a defined category, included in Title 21 of the Code of Federal Regulations as "Part 3—Statements of General Policy or Interpretation." APA's rulemaking procedure does "not apply (A) to interpretative rules, general statements of policy" (§4(a), 5 U.S.C. §553(b).)

present in a shampoo preparation for it to qualify as 'egg shampoo' " (21 C.F.R. 3.651) (Abb. Br. 32).

Petitioners equate such interpretative regulations to both the drug regulations in *Abbott Laboratories*, and the Color Additives Regulations,* and argue pre-enforcement challenge would "substantially affect the administration of the Food and Drug Act" (Abb. Br. 32). However, it is obvious that the formal Regulations,— with their broad scope and arrogation of substantial and far-reaching powers to FDA,—are vastly different from an interpretative regulation as to the egg requirements of a shampoo.

(2) Nor can petitioners escape review by calling the Regulations "Definitions."

The "Definitions" section of a statute can determine its reach and intended agency authority. Rarely, if ever, would a statute specifically provide for judicial review of a regulation purporting to "interpret" a "definition." Yet, a change in statutory definition, by "interpretative" regulation, could be the most effective method to expand agency authority.**

Premier Peat Moss Corporation v. *United States*, 147 F. Supp. 169 (S.D. N.Y. 1956), *aff'd*, 355 U.S. 13 (1957) exemplifies how arbitrary "interpretation" or "definition" can expand agency power. There the court,—illustrating how

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* Though petitioners argue the Color Additives Regulations are mere statements of general policy or interpretation, they were not included in Part 3 of the C.F.R., but in Part 8.

** For example, FDA has jurisdiction over "devices," defined as any "apparatus" which affects the body's structure (§201(h)). A bicycle,—which is an "apparatus" and can affect and improve the body's structure,—fits the definition of "device" more aptly than a finished cosmetic product fits the definition of color additive. If FDA, by regulation, "interpreted" the "devices" definition to include bicycles and thereby subjected them to all the Act's provisions applicable to "devices," bicycle manufacturers clearly could obtain prior judicial review of whether FDA had gone beyond Congressional intent and exceeded its statutory authority.

an interpretation "that tomatoes are not an 'agricultural' commodity" would change the coverage of the Interstate Commerce Act as to a tomato farmer and "deprive him of a statutory right,"—sustained prior judicial review of an "interpretation" that the statutory term "agricultural commodities" did not include peat moss, and held that "the Commission exceeded the limits placed upon its statutory powers" (pp. 172, 174).

Similarly, an FDA "definition" or "interpretation" that "color additive" means lipstick, rouge, eye make-up color and other finished cosmetic products which color the body, immediately affects all cosmetic manufacturers and deprives them of a statutory right.

(3) Furthermore, the Regulations are legislative in nature. They were issued under the "authority" of Sections 701 and 706 of the Act (21 C.F.R., 1966 rev., p. 76). Section 706 authorizes the Secretary "by regulation" to provide for listing and certification of color additives.

Section 701(a), in the 1938 Act, has remained unchanged. Section 706 was derived from Sections 406(b), 504 and 604 of the 1938 Act (52 Stat. 1040), which also authorized the Secretary to "promulgate regulations" for listing and certification. The House Report on the 1938 Act* summarizes its provisions as to regulations for listing and states (pp. 9-10):

> "*Such regulations are not merely interpretive. They have the force and effect of law and must be observed.* Their violation may result in the imposition of criminal penalties, or in the confiscation of the goods involved if shipped in interstate commerce, or in their exclusion from the country if imported."

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* H. R. No. 2139, 75th Cong., 3d Sess., Apr. 14, 1938, U. S. Cong., House Reports on Public Bills, Serial 10234.

Davis, Administrative Law Treatise, states as to "legislative" rules (Vol. 1, §5.03):

> "A legislative rule is the product of an exercise of legislative power by an administrative agency, *pursuant to a grant of legislative power by the legislative body.* * * * A legislative rule is valid and is as binding upon a court as a statute if it is (a) *within the granted power,* * * *." (p. 299)

The "Final Report of the Attorney General's Committee on Administrative Procedure" (1941), using the term "substantive" rather than "legislative" regulation, states that such "regulations have many of the attributes of statutes themselves and are well described as subordinate legislation." (p. 27)

As already noted, FDA proceeded as though it were promulgating regulations intended to have the force of law, carefully following APA's rule making procedure,—a procedure expressly inapplicable "to interpretative rules." (5 U. S. C. §553(b)).

The legislative character of the Regulations is underscored by the fact that FDA itself regarded the matters covered thereby as so legislative in nature that it repeatedly sought legislation granting it the very authority it finally took by the Regulations (see pp. 17-21, *supra*).

Pertinent is *Federal Communications Commission* v. *American Broadcasting Co.*, 347 U. S. 284, 296 (1954), where the agency, in the guise of interpreting a statute, promulgated regulations in excess of its authority. This Court voided the regulations, stating:

> "Likewise, without success, it urged Congress to amend the law to specifically prohibit them ["give-away" programs]. The Commission now seeks to accomplish the same result through agency regulations. In doing so, *the Commission has overstepped*

the boundaries of interpretation and hence has exceeded its rule-making power."

(4) The test of reviewability is not whether a regulation is "legislative" or "interpretative," but its impact on the persons affected,—whether it operates to control their business affairs and other activities, whether it puts them in the position of complying or risking criminal penalties. Whether FDA calls the Regulations interpretative, legislative, substantive, procedural, statements of policy or opinions or concocts a new label, the impact on respondents is the same.

In *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407, 411, 419 (1942), where the "regulation" was described by the Government agency on issuance as merely "'the expression of the general policy we will follow'", this Court rejected an argument, comparable to that here presented, as "addressed to the form rather than the substance of the order".

The Attorney General's Report states that "interpretations may take the form of 'interpretative rules'"; that they are "of considerable importance; customarily they are accepted as determinative by the public at large"; and that "*if there is disagreement with the agency's view, the question may be presented for determination by a court*" (p. 27). This was the law even before the added protection granted by the APA.

Davis, Administrative Law Treatise, quoting from the Attorney General's Report, reaffirms that interpretative regulations are "subject to challenge in any court proceeding in which their application may be in question" (Vol. 1, §5.04, p. 312).

Petitioners, as the District Court stated, give respondents two choices,—"complying with them [the Regula-

tions], at a cost that may prove to be prohibitive for some of the plaintiffs, or ignoring them at the risk of incurring the statutory penalties should the regulations later be held valid" (R. 72). If respondents cannot obtain declaratory adjudication, they must comply; the penalties for noncompliance would be ruinous even if they prevail.*

B. Review of the Regulations is Authorized by an Action in Equity for an Injunction.

As stated in *Terrace* v. *Thompson,* 263 U.S. 197, 216 (1923), parties "are not obliged to take the risk of prosecution, fines and imprisonment and loss of property in order to secure an adjudication of their rights," and therefore "equitable relief may be had."

Stark v. *Wickard,* 321 U. S. 288 (1944),—where the complaint sought to enjoin an order of the Secretary of Agriculture as "without statutory authority" (p. 303),—held the power of administrative agencies is "circumscribed by the authority granted" (p. 309); "The responsibility of determining the limits of statutory grants of authority in such instances is a judicial function entrusted to the courts by Congress by the statutes establishing courts and marking

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* Petitioners make the amazing statement that seizure of cosmetics for non-compliance with listing requirements would not seriously affect a company's reputation "since it would be quite clear to the public what the basis for the seizure is" (Br. 18, fn. 8). Petitioners cannot seriously believe good will would not be affected by headlines of seizure for adulteration, or that news reporters and cosmetic users would understand the seizure was simply a procedural device to test FDA's interpretation of the Act.

In any event, the complaint alleges that mere institution of proceedings "will have a serious, substantial and adverse effect on the business of the company involved * * * and the reputation and integrity of the manufacturer of such cosmetic, and the good will associated with its name, would be forthwith adversely affected, with serious and costly consequences to its business." (R. 24) This allegation must be accepted as true on this motion to dismiss.

their jurisdiction" (p. 310); and, accordingly, "petitioners have shown a right to a judicial examination of their complaint" (p. 311).

Frozen Food Express v. *United States,* 351 U. S. 40 (1956), where the issue of excess of statutory authority was also presented by suit for injunction, applies *a fortiori.* The ICC issued a "report and order" advising the motor vehicle industry of those commodities within and outside the statutory term "agricultural commodities,"—an "interpretation" which determined exemption from its licensing requirement. It resisted advance test of validity, claiming judicial review had to await an enforcement proceeding. The lower court held the order not reviewable because not made in exercise of ICC's "rule-making power," but as a "definition of such statutory term" (128 F. Supp. at 377, 378).

This Court, however, reversed, held "the issues raised in the complaint are justiciable" (p. 45), and in language so apposite it could have been written for this case, stated (pp. 43-5):

> "The situation here is quite different. The determination by the Commission that a commodity is not an exempt agricultural product *has an immediate and practical impact* on carriers who are transporting the commodities, and on shippers as well. The 'order' of the Commission warns every carrier, who does not have authority from the Commission to transport those commodities, that *it does so at the risk of incurring criminal penalties.* §222(a). * * * The 'order' of the Commission which classifies commodities as exempt or nonexempt is, indeed, *the basis for carriers in ordering and arranging their affairs.* Cf. *Rochester Tel. Corp.* v. *United States,* 307 U. S. 125, 132. Carriers who are without the appropriate certificate or permit, because they believe they carry exempt com-

modities, *run civil and criminal risks.* * * * The 'order' of the Commission is in substance a 'declaratory' one, see 60 Stat. 240, 5 U. S. C. §1004(d), which touches vital interests of carriers and shippers alike and sets the standard for *shaping the manner in which an important segment of the trucking business will be done.* Cf. *Columbia Broadcasting System* v. *United States,* 316 U. S. 407. * * * We conclude that the issues raised in the complaint are *justiciable* and that the District Court should adjudicate the merits."

Each factor stated in the italicized language applies to this case precisely; the case is indistinguishable.

Mr. Justice Harlan dissented because the regulation "was not put in the form ordinarily used by the Commission in promulgating regulations" and "nowhere commands" compliance (351 U. S. at 45),—considerations here absent. (See pp. 21-23, *supra.*)*

Equally compelling is *Columbia Broadcasting System, Inc.* v. *United States,* 316 U. S. 407 (1942).

Columbia Broadcasting System ("CBS"), a nation-wide broadcasting network, had contracts with 123 radio stations licensed by the FCC. The regulations—challenged by CBS

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* *Abbott Laboratories* v. *Celebrezze,* 352 F. 2d 286, 288-9 (3d Cir. 1965) (No. 39), distinguished *Frozen Food Express* on the sole ground it "was reviewed under the statutory scheme for review of I. C. C. orders by a specially constituted District Court, 28 U. S. C. §1336." This distinction is fallacious, since Section 1336 does not affect the requirement, applicable to all cases, of a justiciable issue. It does no more for an ICC order than is required for an injunction or declaratory judgment. Had that section removed the requirement of justiciability, obviously this Court would not have considered that issue in *Frozen Food Express.* The Government, in its petition opposing certiorari in *Abbott Laboratories,* stated "we agree that there may be substance to petitioners' contention that the second reason given by the court of appeals [absence of a justiciable issue under the Declaratory Judgments Act] is inconsistent with *Frozen Food Express* v. *United States,* 351 U. S. 40" (p. 4).

as "beyond the Commission's statutory authority",—authorized denial of license renewal if the station's contract with CBS had certain proscribed conditions.

This Court's decision meets every argument here made by petitioners:

(1) The FCC regulations,—unlike the FDA Regulations,—were not issued as "final" regulations, but as "nothing more than the expression of the general policy we will follow in exercising our licensing power" (p. 411, fn. 1). This Court stated the argument as to non-reviewability was one "addressed to the form rather than the substance of the order" (p. 419),—an answer to petitioners' claim that the FDA Regulations are an announcement of what FDA "believes" and a mere expression of "difference of view" (Br. 8, 17).

(2) The FCC regulations were not even directed to CBS; they related only to individual radio stations seeking license. The impact on CBS was derivative. Yet, CBS had standing to obtain judicial review because application of the regulations would "seriously disorganize its business" (p. 414). The FDA Regulations specifically apply to and have a direct impact on respondents.

(3) FCC urged that the regulations did not operate of their own force to deny or cancel a license. Petitioners urge that the Regulations are not reviewable because they have not yet been applied to respondents and no enforcement proceedings have been instituted. (Br. 16-17). This Court, however, stated (417-418):

> "It is enough that failure to comply with them [the regulations] penalizes licensees, and appellant, with whom they contract. *If an administrative order has*

that effect it is reviewable and it does not cease to be so merely *because it is not certain whether the Commission will institute proceedings to enforce the penalty incurred under its regulations for noncompliance* * * *."

C. Review of the Regulations is Authorized by the Declaratory Judgments Act.

The Declaratory Judgments Act was particularly designed to cover the very situation here presented:

> "The [declaratory judgment] procedure has been especially useful in avoiding the necessity, now so often present, of having to act at one's peril or to act on one's own interpretation of his rights, or abandon one's rights because of a fear of incurring damages. So now it is often necessary, in the absence of the declaratory judgment procedure, to violate a statute in order to obtain a judicial determination of its meaning or validity." S. Rep. No. 1005, 73d Cong., 2d Sess., pp. 2-3 (1934).

Declaratory judgment has special application to agency regulations imposing burdens. Thus, as Borchard states:*

> "Possibly in no branch of litigation is the declaration more useful than in the relations between the citizen and the administration. * * *; [a] field of controversy peculiarly susceptible to the expeditious and pacifying ministrations of the declaratory judgment."
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> * * * * * *
>
> "In the twentieth century, * * * there has been a special need for a speedy determination of the constitutionality and construction of legislation and *regulations imposing burdens on the individual.*"

*"Challenging 'Penal' Statutes by Declaratory Action," 52 Yale L. J. 445, 454 (1943).

The Declaratory Judgments Act provided an added remedy "to challenge the validity and scope of the agency's order * * * *even if the agency is not prepared to institute court proceedings to achieve compliance*" (*United States* v. *St. Regis Paper Co.*, 285 F. 2d 607, 615 (2d Cir. 1960), *aff'd*, 368 U. S. 208 (1961)). This Court there indicated that validity of agency orders can be tested by " 'the Declaratory Judgment Act, the Administrative Procedure Act, or general equitable powers of the courts' " "instead of waiting for the Attorney General to sue," "where such orders appear suspect and ruinous penalties would be sustained pending a good faith test of their validity" (pp. 226-7).

See also, *Joint Anti-Fascist Refugee Committee* v. *McGrath*, 341 U. S. 123, 156 (1951); *Wallace* v. *Currin*, 95 F. 2d 856, 861 (4th Cir. 1938), *aff'd*, 306 U. S. 1 (1939).

D. Review of the Regulations is authorized by the Administrative Procedure Act.

This action is authorized by Section 10 of the APA (5 U. S. C. §§701-706,—an Act "to be given a 'hospitable' interpretation" (*Shaughnessy* v. *Pedreiro*, 349 U. S. 48, 51 (1955). It authorizes judicial review of agency action by "any applicable form of legal action, *including actions for declaratory judgments* * * * in a court of competent jurisdiction." (§703) It "sets forth a simplified statement of judicial review designed to afford a remedy for every legal wrong."*

The APA further authorizes "the reviewing court" to (§706):

> "(2) hold unlawful and set aside agency action, findings, and conclusions found to be (A) * * * not

* H. Rpt. No. 1980, May 3, 1946, U. S. Code Cong. Adm. News (1946), p. 1205.

> in accordance with law; * * * (C) *in excess of statutory jurisdiction, authority, or limitations, or short of statutory right*; * * *."

FDA is an agency subject to the APA (§551(1)); the Regulations are within the definition of "rule" (§551(4)); their issuance is "agency action" (§551(13)); and respondents are "adversely affected" (§702). *Flemming* v. *Florida Citrus Exchange*, 358 U. S. 153, 168 (1958).

Though availability of judicial review is amply established in equity and by the Declaratory Judgments Act, *Heikkila* v. *Barber*, 345 U. S. 229, 232 (1953), indicates probable expansion of judicial review under the APA. This Court there stated that "the broadly remedial purposes of the Act *counsel a judicial attitude of hospitality towards the claim that §10 greatly expanded the availability of judicial review.*"

Ewing v. *Mytinger & Casselberry*, 339 U. S. 594 (1950), on which petitioners place such reliance (Abb. Br. 7, 24-5, 30, 45, 47; Br. 14), is not remotely in point. The issue there was not reviewability of a final agency regulation, but of an agency's finding of "probable cause," prerequisite to filing a libel action for misbranding. This Court described such finding as "a preliminary step in a judicial proceeding" and the request for such review as "unique" (339 U. S. at 600). The effect of granting judicial review would have been to "stay the institution of seizures" of products then being marketed, denying the public the "speedy protection which Congress provided by multiple seizures" (p. 601).

Such considerations are obviously not present here. On the contrary, judicial review of the Regulations in this declaratory proceeding will assure not only the public but all concerned the speediest possible resolution of the disputed issues.

II.

Congress did not intend to preclude pre-enforcement judicial review of FDA regulations challenged as in excess of statutory authority. This is shown on the face of the Act and in its legislative history.

It is petitioners' cornerstone contention that the Act contains a "'highly selective' pattern of review—marked by Congress' specific enumeration of instances when it wished pre-enforcement judicial review and its *silence* when it did not" (Br. 14). They maintain that the only regulations Congress intended be so reviewed are those issued under sections specified in Section 701(e)(1), or those issued under a section which specifically applies Section 701(e)(1), such as Section 706(d), and as to which review is by administrative hearing (the "special statutory procedure"), with direct appeal to the Court of Appeals which must treat the agency's findings as conclusive "if supported by substantial evidence".

Asserting the Act is silent as to pre-enforcement judicial review of all other regulations, petitioners find what is "characterized as 'implied statutory exclusion' of judicial review." (Abb. Br. 23).

Petitioners overlook certain fundamental considerations.

First, the responsibility of determining whether an agency exceeded statutory authority is a judicial function. Mere silence as to judicial review is not construed as denial of authority to aggrieved persons to seek relief in the federal courts in exercise of their general jurisdiction. *Stark* v. *Wickard*, 321 U. S. 288, 309-10 (1944). To preclude such judicial review of a regulation, the statute "'*must upon its face give clear and convincing evidence of an intent*

to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of an intent to withhold review.' " *Heikkila* v. *Barber*, 345 U. S. 229, 232 (1953).

The Act does not on its face contain any evidence of Congressional intent to withhold judicial review or to deny the general review jurisdiction vested in the federal courts. Neither the alleged " 'implied statutory exclusion' of judicial review" nor "the legislative history" upon which petitioners rely (Abb. Br. 11-26) satisfies the test that Congressional intent must appear on the face of the statute by clear and convincing evidence.

In *Gonzalez* v. *Freeman*, 334 F. 2d 570 (D. C. Cir. 1964), to defeat challenge to agency regulations as in excess of statutory authority, it was also urged that since the applicable statute,—the Commodity Credit Corporation Act (15 U. S. C. §714(b)),—was silent as to judicial review, this showed none was intended. The Court held (334 F. 2d at 575):

> "We find no such intent reflected in the statute. * * * 'the responsibility of determining *the limits of statutory grants of authority in such instances is a judicial function entrusted to the courts by Congress* * * *' Stark v. Wickard, 321 U. S. 288, 310, 64 S. Ct. 559, 571, 88 L. Ed. 733 (1944).
>
> "* * * Nothing in the statute confers unreviewable finality on determinations of the Secretary *as to questions of the scope of his congressional authority* * * *."

Second, as the Court of Appeals stated, "The agency determinations specifically reviewable under §701(e)* re-

* Section 701(e)(1) covers §401, as to standards of identity and quality for food; §403(j), as to labeling information for a food's

late to * * * technical subjects'' within FDA's expertise, and Congress ''did not wish courts to consider such matters without the benefit of the agency's views after an evidentiary hearing before it'' (R. 129-30). However, the scope of the Commissioner's statutory authority is a legal issue as to which the court rather than the agency has the requisite expertise.

Third, the Act is not silent as to other remedies. It plainly provides in the Section 701(f) saving clause that:

> ''(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law''.

The House Report on the 1938 Act* stressed that ''any individual or business organization'' affected by FDA regulations may proceed by declaratory judgment and suit for injunction to enable prompt determination of their validity and certainty as to legal rights. Thus, the Report, referring to the saving clause, states (p. 11):

> ''There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.''

Petitioners nevertheless argue that the saving clause applies only to regulations specifically made reviewable

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vitamin, mineral and other dietary properties; §404(a), as to food contamination during manufacturing or packing; §406, as to limiting poisonous substances required in food production; §501(b), as to testing strength, quality and purity of certain drugs; §502(d), as to drugs, containing habit forming narcotics; §502(h), as to packaging drugs liable to deterioration; and §706 as to listing and certifying colors, including quantity of a dye which may be safely used in food, drugs and cosmetics, the cumulative effect of such dye in the diet of man or animals, and like technical matters.

* Rep. No. 2139, 75th Cong., 3d Sess., dated April 14, 1938.

under Section 701(e) (Abb. Br. 26-7),—a narrow construction not accepted by either court below; both held such clause preserved all other remedies provided by law (R. 52, 139).* The saving clause was obviously designed to preserve the broadest possible judicial review, as its legislative history so clearly establishes. It foreclosed a construction that the special statutory procedure precluded appropriate relief in the federal courts *(Cf. Stark* v. *Wickard,* 321 U. S. 288, 309 (1944)), and made it clear that even as to those regulations to which the special statutory procedure applied, the aggrieved person could proceed in equity by declaratory judgment or any other remedy provided by law.

Petitioners' position would produce an anomalous result. It would provide two types of review for regulations covered by Section 701(e)(1) and deny all pre-enforcement review of a regulation whereby the agency exceeded its powers.

There was no need for Congress expressly to preserve judicial review of challenge of statutory authority, since the power of review in equity by injunction and declaratory judgment is inherent in federal courts and implicit as to every agency, unless a statute on its face specifically withholds such judicial review or expressly prescribes a special and exclusive remedy.** *Stark* v. *Wickard,*

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* The Court of Appeals noted (R. 130, fn. 7) that the accompanying minority report "indicated that the special procedure was understood to be an additional protection for industry and not an exclusive method of review of all actions for the benefit of the agency. H.R. Rep. 2139, Pt. 2 (April 21, 1938)."

** The Government itself brings this out in its *Abbott Laboratories* brief (p. 13), which notes that the House considered it unnecessary to incorporate a review provision because " '[t]here is always an appropriate remedy in equity * * * and furthermore the committee is of the opinion that ample protection is given by the so-called Declaratory Judgments Act * * *.' H. Rept. No. 2755, 74th Cong., 2d Sess. (1936), p. 8, *Dunn* 557."

321 U. S. 288, 309-10 (1944); *Heikkila* v. *Barber*, 345 U. S. 229, 232 (1953). The House Report emphasized that the fact the Act did not affirmatively deny judicial review to FDA regulations indicated an intent to authorize the broadest kind of judicial review and to hold a regulation invalid "if for any other reason it was not in accordance with the law" (Rept. No. 2139, p. 12):

> "The committee amendment *is silent* as to any limitations on the court in holding invalid the order of the Secretary. *The court is thus left free to exercise its right of review to the full extent that it may constitutionally do so.* * * *"

It is clear beyond question, as the Court of Appeals stated, that Section 701 does not indicate Congressional intent "to insulate administrative action not covered by subsection (e) from challenge as in excess of statutory authority" (R. 130).

III.

The Regulations have immediate impact on respondents and are ripe for judicial review.

Petitioners argue that only after the color ingredient in the cosmetic has been listed and certified will the question arise "whether respondents must also obtain separate listing and certification or exemption therefrom for their particular finished color-imparting cosmetics before these products may be offered for sale" (Br. 17). Then "the issue of statutory construction will be squarely presented, in a concrete case, to a court of appeals" under the special statutory procedure (Br. 18). Therefore, "no present obli-

gation" is imposed on respondents and their "injury is distant and speculative" (Br. 17).

This argument misdescribes the Regulations and bears no relationship to their text or announced purposes or to FDA testimony as to their meaning and impact.

The Act is plain. It pronounces as adulterated and prohibits sale of any article of food, drug or cosmetic containing a color additive not listed in a regulation and certified, unless exempted (§304(a), 601(e), 706(a)). This applies immediately to everything that is a color additive. The Regulations, defining color additive to include not only the color but the finished cosmetic product which contains the color, became "effective on the date of its publication in the Federal Register", June 22, 1963, though the portions as to diluents and hair dyes were made effective, respectively, one and two years later (28 Fed. Reg. 6439, 6449). When FDA defined "color additive" to include "Lipstick, rouge, eye make-up colors, and related cosmetics intended for coloring the human body" (§8.1(f)), the listing and certification requirements automatically became applicable to such cosmetics at the same time they became applicable to the dye, pigment or other color ingredient.

There is nothing in the Regulations which provides, or even suggests, that the listing requirement applies at one time to the color ingredient and at a later time to the cosmetic product itself.*

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*Respondents, in compliance with the requirement for listing dyes and pigments, had by December 3, 1965, filed petitions to list 16 separate colors "for use in drugs and cosmetics that are applied externally" (R. 94-5). A Government affidavit states that "Because of the pendency of this lawsuit, these petitions have not yet been acted upon" (R. 97). This is inconsistent with petitioners' position that the Regulations first require listing of the color, and thereafter, at some future date, possible separate listing of the cosmetic containing the color. If listing of colors, which it is agreed is required by the Amendments and the Regulations, must

The "present obligation" and burdens of the Regulations have been described (pp. 23-25, *supra*). The required testing of finished cosmetic products, prerequisite to listing, would have to be promptly commenced and diligently pursued. The Regulations have "an immediate and practical impact" on the entire cosmetic industry and set "the standard for shaping the manner in which" its business is operated. *Frozen Food Express* v. *United States,* 351 U.S. 40, 44 (1956).

The Court of Appeals correctly held the Regulations have "immediate impact on the industry, posing the unacceptable alternatives of complying or of incurring possible forfeitures and criminal liability, and calling into question long standing practices of premarketing testing and clearance" (R. 136). Respondents' injury is not "distant."

However, even if petitioners correctly describe the Regulations as delaying listing of the finished product until after listing of the color ingredient, that would not make the Regulations unripe for review. In *Flemming* v. *Florida Citrus Exchange,* 358 U. S. 153, 168 (1958), where legislation delayed for three years the effectiveness of the Secretary's order delisting certain colors, this Court held "the facts of the respondents' business are such that if the order is upheld, there will be a practical effect on them even during the span of the temporary legislation" and, accordingly, "it is proper for us now to determine the legal situation in regard to them when the temporary legislation expires."

Nor is there basis to the argument respondents' injury

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precede listing the finished cosmetic product, there is no reason why action on the color listing petitions should be delayed merely because respondents challenge FDA's power to require listing of the finished cosmetics.

is "speculative" because FDA might never require separate listing and certification of the finished cosmetics. If such products are in fact color additives, as the Regulations provide, then listing is mandatory, even for cosmetics in use for over 50 years and generally recognized by qualified experts as safe. The Act grants FDA power to exempt color additives only from certification, not from listing.

The Regulations are neither "distant" nor "speculative" and are ripe for judicial review.

IV.

The special statutory procedure is inapplicable to the issue of excess of authority.

Petitioners suggest that if in the future the provision requiring listing of finished cosmetic products is applied to a particular respondent, he can follow "the administrative procedure specifically authorized under the statute", and then "the issue of statutory construction will be squarely presented, in a concrete case, to a court of appeals under the judicial review procedures of Section 706(d), which incorporates Sections 701(e), (f) and (g)" (Br. 16, 18). However, the special statutory procedure is clearly not designed to adjudicate issues of exceeding statutory authority. As the District Court stated, "it is scarcely to be thought that judicial review limited to the traditional and narrow scope of whether or not the Commissioner's findings are supported by adequate evidence can supplant the other and broader form of remedy or review available under the Declaratory Judgment Act." (R. 52)

Existence of special agency procedures does not require an aggrieved party to first go before the agency where, as

here, the issue is exceeding statutory power. In *Skinner & Eddy Corp. v. United States,* 249 U. S. 557 (1919), this Court held that a party challenging ICC orders could proceed immediately in the district court because "The contention is that the Commission has exceeded its statutory powers; and that, hence, the order is void. In such a case the courts have jurisdiction of suits to enjoin the enforcement of an order, even if the plaintiff has not attempted to secure redress in a proceeding before the Commission" (p. 562).

Nowhere do petitioners indicate how an issue of excess of statutory authority is even presented in FDA's special statutory procedure. Assuming FDA should by regulation list a particular dye for use in a lipstick and specify the tolerance or quantity used, and a cosmetic manufacturer filed objections urging a different quantity, how could this conceivably present the issue whether FDA has power to require that the finished cosmetic product itself be listed and subjected to the certification requirement?

FDA itself has taken the position such an issue could not be determined in an agency hearing. When challenge was made to the Commissioner's authority to promulgate certain regulations under the "Drug Abuse Control Amendments of 1965" (79 Stat. 226), which authorized regulations as to depressant and stimulant drugs with review under the special statutory procedure, the Commissioner refused even to allow the objections to be filed since they were "concerned with the Commissioner's authority under the act to promulgate the inventory requirement regulations. *This is a question of law and cannot be resolved by the taking of evidence at a public hearing.*" (31 Fed. Reg. 7174, May 17, 1966).

In fact, petitioners, disagreeing with the District Court's decision to have a trial (R. 75-76), now assert "that the issues of statutory construction can be resolved without evidentiary proceedings and that the record is now adequate to resolve them."* (Br. 20, fn. 9). This statement is irreconcilable with their position that respondents are limited, absent an actual enforcement proceeding, to an administrative hearing with direct review in the court of appeals.

V.

FDA arrogation of power to obtain "free access" to cosmetic formulae is also subject to judicial review in equity, by declaratory judgment and under the APA.

The Court of Appeals, without the issue having been separately considered, held the "free access" provision not reviewable. The correctness of this is the subject of No. 336.

The "free access" provision differs from the others in one primary respect. Compliance with the listing obligation requires immediate action by all respondents, who would have to commence testing and file petitions. The "free access" clause, however, requires nothing of respondents until arrival of the FDA inspector, when the decision

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*Petitioners took the opposite position in the District Court. They there successfully opposed summary judgment with the curious argument that "The substantive issue * * * is whether defendants have exceeded their statutory authority in promulgating the specific regulations here at issue. This issue requires an examination of the statute and the applicable regulations, the recognition of clearly delineated legal principles and the application of common sense and reason. Accordingly, defendants do not regard summary judgment as an appropriate procedural remedy * * *". (Defendants' Memo. in opposition to Plaintiffs' Motion for Summary Judgment, undated, pp. 49-50).

must be made either to allow access and abandon rights for fear of penalties or deny access and face penalties.

The Court of Appeals held the issue remote and, therefore, found unripeness; each reason given (R. 137-8) is in conflict with applicable decisions of this Court.

A. The Permissive Language of the "Free Access" Provision and the Fact It Does Not Impose a Present Obligation on Respondents Do Not Preclude Judicial Review.

The "free access" provision was also promulgated pursuant to APA's rulemaking procedure; general notice of proposed rulemaking was published, ostensibly to enable interested persons to comment;* and the final provision was published June 22, 1963, effective immediately. (See pp. 21-23, *supra.*)

As shown above (pp. 17-21), FDA long wanted access to food and cosmetics formulae and in 1962 sponsored legislation to "remedy this problem" of denial of access, and allow "complete inspection" of all processes. After Congress limited inspection of processes and formulae to prescription drugs, and a new FDA attempt the following year also failed, FDA took the "free access" power, warning that refusal of access could cause the cosmetic to be banned from the market (R. 106-7).

FDA counsel Goodrich had stated "the need is real" and FDA will "continue with all our abilities to urge the Congress to meet the need."** (See p. 20, *supra.*)

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* As already noted, the provision giving "free access" to formulae of finished cosmetic products was not in the original notice of proposed rule-making (p. 22, fn. *supra*).

** Petitioners' original brief in the District Court, undated, and served March 3, 1964, pp. 49, 50, also stressed FDA's need for "free access" to cosmetic formulae, making substantially the same argument FDA had presented to Congress; namely, that such access was "plainly needful for the effective enforcement of the

Such assertions, coupled with its persistence in seeking the "free access" authority from Congress, makes it unlikely FDA will refrain from exercising the power taken by regulation. It is unrealistic to assume, as the court below did, that the possibility is "remote" because "No one can now say whether the Commissioner will ever make a demand for free access" (R. 137).

FDA use of "may" rather than "will" can hardly soften the impact on the cosmetic industry of the power it illegally took or its warning it may "ban it [the product] from the market" (R. 106-7).

Vicksburg Waterworks Co. v. *Vicksburg,* 185 U. S. 65, 82 (1902) rejected a contention that "mere apprehension that illegal action may be taken" was insufficient basis to enjoin such action, and held "it is one of the most valuable features of equity jurisdiction, to anticipate and prevent a threatened injury," and to protect a party "from injuries which, *if inflicted,* would be wholly destructive of his rights."

Similarly, *Pierce* v. *Society of Sisters,* 268 U. S. 510, 536 (1925) held that suit to enjoin a statute not to become effective for four years was not premature, and that "Prevention of impending injury by unlawful action is a well recognized function of courts of equity."

In *Joint Anti-Fascist Refugee Committee* v. *McGrath,* 341 U.S. 123, 141 (1951) where, as at bar, the official charged

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Act," and that the Commissioner "must have access to the plants where they [the cosmetics] are made" and to cosmetic formulae, since "There is no other way in which the Commissioner" can perform his functions.

Similarly, affidavits of Oscar Garth Fitzhugh and Kenneth A. Freeman, of FDA's Bureau of Scientific Standards and Evaluations, sworn to, respectively, May 26, 1964 and May 22, 1964, submitted in support of the "free access" regulation, stated that FDA "must know the exact formula of the product" (Fitzhugh, ¶2), and that "it is necessary that we have a full disclosure of all the ingredients in any color additive," defined to mean finished cosmetic products (Freeman, ¶4).

with exceeding statutory authority did nothing directly affecting the petitioners, this Court stated "We long have granted relief to parties whose legal rights have been violated by unlawful public action, *although such action made no direct demands upon them.*"

Particularly pertinent is *Columbia Broadcasting System, Inc.* v. *United States,* 316 U.S. 407 (1942). There the regulations were not issued as "final", nowhere demanded compliance and, as in the case of the "free access" provision, required action by the agency. This Court, however, held the regulations were subject to prior judicial review even though they "are not directed to appellant and do not in terms compel action by it or impose penalties upon it because of its action or failure to act" (p. 422). It further held that reviewability was unaffected by the fact that the regulations were "not directed to any particular person or corporation," or that "their promulgation did not operate of their own force * * *" (p. 417). "*Such regulations have the force of law before their sanctions are invoked as well as after*" (p. 418).

The holding below that the "free access" regulation is not ripe for review because it merely warns that "the Commissioner may—not that he inevitably will" enforce the regulation, is as stated in that case, "addressed to the form rather than the substance" (p. 419).

This Court also held that an administrative order is reviewable where there is risk of penalty, and "it does not cease to be so merely because it is not certain whether the Commission will institute proceedings to enforce the penalty * * *" (pp. 417-8). This Court also said,—in language which answers the Court of Appeals' statement that "No one can now say * * * whether any manufacturer will ever decline" requested access (R. 137), that:

"It is common experience that men conform their conduct to regulations by governmental authority so as to avoid the unpleasant legal consequences which failure to conform entails" (p. 418);

"* * * the expected conformity to them causes injury cognizable by a court of equity" (p. 419).

Reviewability of the "free access" clause is also unaffected by the fact that the Regulation is not couched as a direct grant of access authority but indirectly accomplishes the same result, through the penalty of banning the product from the market, with all the consequences attendant on illegal sale.* For, as this Court stated, "it is the substance of what the [agency] has purported to do and has done which is decisive" (p. 416).

Equally apt is *Frozen Food Express* v. *United States,* 351 U. S. 40 (1956) where the regulation, as Mr. Justice Harlan's dissent noted, likewise "nowhere commands" compliance (p. 45). This Court, sustained reviewability because the order, which was issued as an announcement rather than a final regulation, "warns" the industry that violation would involve "the risk of incurring criminal penalties," so that it is not "abstract, theoretical, or academic," but "touches vital interests" of the industry there involved (p. 44),—language which shows the error in the decision below that this "free access" regulation is not reviewable because it "simply warns the industry" (R. 137).

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* Had FDA used in the Regulations the exact language of the 1962 proposed amendment which Congress had deleted, there still would be "nothing to indicate that the Commissioner intends to invoke the factory inspection provison in any particular case" (Br. 21). The proposed amendment merely "authorized" inspection (§704(a)). It was no less permissive in language, or more certain as to the person against whom it might be directed than the "free access" provision. Yet, in such event the usurpation of power would be so crude, it is unlikely any court would use the permissive aspect to deny pre-enforcement judicial review.

In *United States v. Storer Broadcasting Co.*, 351 U. S. 192 (1956), "ripeness" for review was found although, as the dissent noted, the petitioner did not allege "present injury of any kind", the challenged regulations "impose no duty" and there was no "possibility of criminal penalties" (pp. 209, 212, 212 fn. 3). There this Court also noted that in the *Columbia Broadcasting System* case the regulation held reviewable "did not command CBS to do or refrain from doing anything" (p. 198).

B. Availability of an FDA Hearing Does Not Preclude Pre-Enforcement Judicial Review.

The court below denied reviewability partly because of availability of an FDA hearing, with possible review by a court of appeals (R. 137), an argument petitioners also now urge (Br. 21). However, the hearing authorized by the Regulations relates only to "the factual basis for the suspension" §8.28(b). If court of appeals review should be available, the findings as to the "factual basis" for banning the cosmetic from the market, "if supported by substantial evidence, shall be conclusive" (§701(f)(3)).

The factual basis for suspension would be self-evident; namely, the manufacturer's refusal to permit "free access" to cosmetic formulae and trade secrets. The only issue in an FDA hearing would be whether access was denied, as to which there would be no dispute. The hearing would not even present the issue whether FDA had exceeded its statutory authority. As noted above, FDA takes the position that the issue of its authority under the Act "is a question of law and cannot be resolved by the taking of evidence at a public hearing." (p. 50, *supra*). The only issue in the court of appeals would be whether there was substantial evidence that FDA access had been denied.

The above discussion as to the first three challenged provisions establishing that the special statutory procedure to review FDA regulations is inappropriate to review issues of exceeding authority and, in any event, is not the exclusive remedy (pp. 49-51, *supra*), applies equally to the issue of FDA's power to require "free access" to cosmetic formulae.

C. A Proper Declaratory Judgment Can Be Issued.

The court below also stated as a reason for not reviewing the "free access" regulation, that "it is impossible to see what declaration a court could properly make" (R. 137), —a point not raised below in briefs or oral argument. The answer is simple. The declaration would be that the provisions of §§8.1(f) and 8.28(a)(4) of the Regulations granting "free access" to cosmetic formulae and processes are not authorized by the Act and are in excess of statutory authority. In effect, these provisions would be deemed deleted from the Regulations.

It should be no ground for refusing to hear a declaratory judgment action that an appellate court may have difficulty at the threshold, and without the merits before it, to see what declaration the District Court could make on the merits, especially when the District Court saw no such difficulty and found "compelling reasons for assuming jurisdiction" (R. 73).

D. The Desirability of Reviewing the Four Provisions of the Regulations Together.

One final significant factor may be noted. Were the only illegal provision the "free access" provision it would be reviewable. However, the reasons for review are heightened, and apply *a fortiori*, because this provision does not stand alone but, as the District Court so aptly stated, "these

four provisions are interrelated as elements of a common plan of governmental regulation" and "there is a distinct advantage in reviewing them together" (R. 73).

The Court of Appeals erred in reversing as to the "free access" provision, which, as may be parenthetically noted, satisfies every test contained in the APA (pp. 40-41, *supra*). Such provision should be reviewed, together with the three other challenged provisions of the Regulations.

VI.

The Abbott Laboratories case presents an entirely different type of regulation from the Color Additives Regulations and is distinguishable.

While the *Abbott Laboratories* case and the case at bar both broadly involve the issue of pre-enforcement judicial review of agency regulations by injunction, declaratory judgment and under the APA, the cases involve different types of regulations. While respondents believe *Abbott Laboratories* was wrongly decided below, should this Court affirm, that would not control reviewability of the Color Additives Regulations.

Although the Court of Appeals stated *Abbott Laboratories* "is not distinguishable on any satisfying basis" (R. 135), respondents submit that the District Court properly held that the situation at bar "is significantly different" from *Abbott Laboratories* (R. 50).

Abbott Laboratories does not present a regulation whereby FDA took new and different powers from those authorized by the Act. There Congress had imposed a specific requirement on the drug industry, namely, that a drug's generic name be "printed prominently" on its label "in type at least half as large" as any brand or proprietary

name (§502(e)(1)(B)). Congress, therefore, clearly intended the requirement that the generic name appear "prominently". Presumably, this requirement could, as the District Court stated, "be satisfied in a number of ways" (R. 50).

However, under the challenged regulation, FDA provided that the "prominently" requirement could be satisfied only if the generic name appears "each time" the brand or proprietary name is used (21 C.F.R. §1.104(g)(1)). FDA, interpreting the word "prominently", in effect determined there was only one way whereby it could be satisfied, except to the extent exemptions might be established because compliance with such requirement was impracticable (§502(e)(1)(B)). FDA was thus acting in a narrow area of drug labelling, in which Congress had specifically legislated and as to which it intended FDA to function. But FDA took what appears to be arbitrary action contrary to Congressional intent.

The Color Additives Regulations obviously present a "significantly different" situation. Congress never authorized premarketing clearance of cosmetics, or their noncolor ingredients, or broad coverage of hair dyes, or access to cosmetic formulae, and never intended FDA to take action in such areas. But by the Regulations, FDA reached out, brought under its control and imposed premarketing clearance requirements on an entire industry, and assumed other authority Congress had repeatedly declined to legislate.

Regardless of this Court's disposition of *Abbott Laboratories*, all four challenged provisions of the Regulations should be held reviewable by injunction, declaratory judgment and under the APA.

Conclusion.

For the foregoing reasons, it is respectfully submitted that the judgment of the Court of Appeals with respect to the First, Second and Third Counts of the complaint should be affirmed, and its judgment with respect to the Fourth Count should be reversed. The case should be remanded to the District Court with instructions to determine whether the four challenged provisions of the Regulations are in excess of statutory authority.

December 30, 1966.

Respectfully submitted,

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APPENDIX.

The Administrative Procedure Act, 60 Stat. 243 (1946), 5 U. S. C. §1001, *et seq.*, recodified in 5 U. S. C. §551, *et seq.* (Public Law 89-554, 80 Stat. 378), provides in pertinent part:

§551. Definitions

For the purpose of this subchapter—

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, • • •

• • • • • •

(4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. • • •

• • • • • •

(13) "agency action" includes the whole or a part of an agency rule. • • •

§553. Rule making

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"(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; * * *

§706. Scope of review.

To the extent necessary to decision and when presented, the reviewing court shall * * * (2) hold unlawful and set aside agency action, findings, and conclusions found to be (A) * * * not in accordance with law; * * * (C) in excess of statutory jurisdiction, authority or limitations, or short of statutory right. * * *

Color Additives Regulations.

21 C. F. R. 8.1(f) provides in pertinent part:

A "color additive" is any material, not exempted under section 201(t) of the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting a color thereto. This includes all diluents. * * * A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are "color additives." * * * For the purposes of this part, the term "color" includes black, white, and intermediate grays, * * *.

21 C. F. R. 8.4 provides in pertinent part:

Petitions proposing regulations for color additives.

(a) Any interested person may propose the listing of a color additive for use in or on any food, drug, or

cosmetic or for coloring the human body. Such proposal shall be made in a petition in the form prescribed in paragraph (c) of this section. • • •

(c) Petitions shall include the following data and be submitted in the following form:

• • • • • •

D. Full reports of investigations made with respect to the safety of the color additive.

(A petition will be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the color additive will be safe for its intended use. The reports ordinarily should include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any data that would influence the evaluation of the safety of the color additive).

21 C. F. R. 8.26 provides:

Records of distribution.

(a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the color additive from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee acting on behalf of the Secretary of Health, Education, and Welfare, such person, at all reasonable hours until at least 2 years after disposal of all such color additive, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color additive on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show:

(1) Each quantity used by such person from such batch and the date and kind of such use.

(2) The date and quantity of each shipment or delivery from such batch, and the name and post-office address of the person to whom such shipment or delivery was made.

(c) The records required to be kept by paragraph (a) of this section shall be kept separately from all other records.

21 C. F. R. 8.28(a) provides in pertinent part:

Authority to refuse certification service.

(a) When it appears to the Commissioner that a person has:

* * * * * *

(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived; he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

21 C. F. R. 8.30(a) provides:

Color additive mixtures; certification and exemption from certification.

(a) *Color additive mixtures to be certified.* Any color additive mixture that contains one or more straight colors listed in Subpart C, E, or G, together with any diluents listed in such subparts for use with such straight colors, shall be certified if intended for use in foods, drugs, or *cosmetics*, or in coloring the human body, as the case may be, subject to any restrictions prescribed in Subparts A and B.

21 C. F. R. 8.50 provides in pertinent part:

Fees for listing.

(a) Each petition for the listing of a color additive shall be accompanied by a deposit of $3,000.00 if the proposal is for listing the color additive for use generally in or on foods, in or on drugs, and in or on cosmetics.

(b) If the petition for the listing is for use in or on foods only, the deposit shall be $3,000.00.

(c) If the petition for the listing is for use in or on drugs and/or cosmetics only, the deposit shall be $2,600.00.

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(j) The fee for services in listing a diluent under §8.30 for use in color additive mixtures shall be $250.00.

21 C. F. R. 8.51(a) provides:

Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with §8.22(j) (1) and (2), shall be 15 cents per pound of the batch covered by such requests, but no such fee shall be less than $100.00.